

"Express Mail" mailing label number \_\_\_\_\_

Date of Deposit \_\_\_\_\_

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Printed Name \_\_\_\_\_

Signature \_\_\_\_\_

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	Dally, et al.,	)	
			)	
Serial Number	:	10/597,241	)	Group Art Unit:
			)	1624
Filed:	:	July 18, 2006	)	
			)	
For	:	SELECTIVE ESTROGEN RECEPTOR	)	Examiner:
		MODULATORS FOR THE TREATMENT	)	Coleman, B. L.
		OF VASOMOTOR SYMPTOMS	)	
			)	
Docket No.	:	X-16604M	)	

**RESPONSE**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The present paper is filed in response to the Office Action dated May 18, 2009.

### **Introduction**

Claims 1-13 and 18-28 are pending in the instant application.

Claims 1-13 and 18-28 are subject to a restriction requirement.

### **Restriction Requirement**

Claims 1-13 and 18-28 stand subject to a restriction requirement under 35 U.S.C. §121 and 372. The Examiner has divided Applicant's claims into three groups – compounds where m is 0 (pyrrolidine compounds), compounds where m is 1 (piperidine compounds), and compounds where m is 2 (azepane compounds) on the basis that they are “structurally dissimilar.” Applicants traverse this restriction requirement and request withdrawal of same. Applicants elect with traverse Group II.

According to the Examiner, Applicant's claims are directed to a group of inventions “which are not so linked as to form a general inventive concept under PCT Rule 13.1.” To support the restriction requirement, the Examiner states:

“[The three groups of compounds] are made and used independently. One does not require the other for their use. If, say, the azepane substituted compounds of formula I and II where m = 2 of Group III, were anticipated, applicants would not acquiesce in the objection of any of the Groups I-II there over or vice-versa and, thus, they are not linked to the same or corresponding special technical features.”

Applicants respectfully assert that each of these bases put forward by the Examiner to support restriction of Applicant's invention is factually inaccurate and/or is a non sequitor to the finding that “no general inventive concept” exists across Applicant's claimed invention.

With respect to the “made and used independently” prong, Applicant's direct the Examiner's attention to Scheme 1 on page 10 of the present application which shows that compounds where m is 0, 1 or 2 are all made by the same general procedure.

With respect to the lack of dependence of one group on the other for “their use”, Applicants respectfully inquire whether a claim directed to a genus of compounds alleged to be useful for human therapy would ever not be subject to a restriction requirement. In such a case, this portion of the Examiner's logic would require separate examination of every single species encompassed by the claimed genus.

With respect to the Examiner's anticipation example, if a species falling within the scope of Group III (a genus of compounds) were found to anticipate Group III, that species,

by definition, would not fall within the scope of Groups I and II and therefore not anticipate claims directed to those other groups. In such a circumstance, an Applicant would not reasonably acquiesce to such an allegation if one were made in that context. Thus, it is respectfully asserted that a disagreement regarding anticipation is a non sequitor to the Examiner's restriction of the present claims.

Moreover, Applicants respectfully direct the Examiner's attention to the specification at page 2 where it states, "Many publications have appeared within the last ten years disclosing selective estrogen receptor modulators (SERMs), *e.g.*, U.S. Patent No.'s 5,484,795, 5,484,798, 5,510,358, 5,998,401 and WO 96/09040." In many, if not all, of these publications, pyrrolidine, piperidine and azepane compounds are described and claimed in Markush groups.

Reconsideration of the restriction requirement is respectfully requested.

Respectfully submitted,

/Gilbert T. Voy/

Gilbert T. Voy  
Attorney for Applicants  
Registration No. 43,972  
Phone: 317-276-2966

Eli Lilly and Company  
Patent Division/GTV  
Lilly Corporate Center  
Indianapolis, Indiana 46285  
June 18, 2009